



Call For proposal 2020-2021 Influenza Season

GLOBAL ACTIVE INFLUENZA HOSPITAL SURVEILLANCE NETWORK LINKING CLINICAL AND VIROLOGICAL DATA

OBJECTIVE

The biannual seasonal influenza vaccine strain selection process that drives the vaccine composition decisions remains challenging and enhanced data from surveillance monitoring and virology sequencing (timeliness, geographic representativeness, clinical relevance) are most needed.

We are looking for non-profit public institutions who can oversee a network of hospitals and follow a standardized protocol¹ to be part of the GIHSN.

GIHSN evolution to emphasize clinical and virologic data (including WGS) in influenza positive patients began during the 2019/2020 season. However, the COVID-19 pandemic highlights the importance of diagnostic and epidemiologic data for both influenza positive and influenza negative patients. While critical to maintain our primary network focus on influenza, inclusion of data and maintaining samples from influenza negative cases allows for expansion, if needed, of our network to rapidly include other pathogens of interest (e.g. COVID-19). This ongoing pandemic also highlights the importance of rapid sharing, when possible, of GIHSN SARI laboratory and epidemiologic data with the global health community through platforms such as GISAID.

As such, the following specific objectives are highlighted for the 2020/21 call for tender:

- Real time completion of e-CRF (weekly) for both positive and negative influenza cases. COVID-19 diagnostics results should be reported if testing has been performed.
- Storage (-20C or -70C) of all influenza positive and negative SARI samples for a minimum of one year with a subset of 30% stored for an additional 3 years. This will assure sample availability for additional retrospective investigations (e.g. COVID-19) if necessary.
- WGS of 50 to 100 influenza positive samples with use of specific selection criteria to be agreed upon. WGS data will be uploaded to GISAID in a timeframe so that results are available for the site's respective WHO Vaccine Composition Meeting (VCM).

¹ See the protocol on the GIHSN website www.gihsn.org
Foundation for Influenza Epidemiology - GIHSN Call for tender 2020-2021

ELIGIBILITY CRITERIA

Applicants should be non-profit public institutions and will be asked to provide substantiating documentation when submitting their application. (*See How to apply*)

All sites must show an excellent connection between a hospital surveillance platform and a virology laboratory in their country, allowing the possibility for confirmed influenza by RT-PCR and subsequent sequencing of the positive specimens in less than 7 days. If no capacities to generate genetic sequence data (GSD) are available, the site may ship its specimens to the GIHSN sequencing platform at the National Influenza Center in Lyon, France, under the Terms of Reference for sharing materials in GISRS. Shipment expenses will be borne by the GIHSN.

All sites must have the capacity to submit GSD (optional) and submit at a minimum consensus data of the HA and NA segments to the GISAID EpiFlu™ database². Clinical information will be captured in the current e-CRF used by the GIHSN and includes the link with the GSD and other metadata shared through GISAID.

SELECTION PROCESS

Applications from Institutions meeting the eligibility criteria will be reviewed and evaluated by the Independent Scientific Committee of the Foundation according to predefined quality criteria.

Main evaluation criteria are:

- Laboratory capacities: The existing full genome sequencing capacities on site or proposed referral system to sequence Influenza positive samples should be described.
- Targeted sample size: The estimated number of sequenced samples expected to be shared via the GISAID platform during the Influenza season is between 50 and 100.
- Clinical information data collection capacities: The site needs to describe the way and the method to access clinical information (using laboratory referral system or using targeted clinical sampling)
- Timelines of the data availability: Sites should be able to upload data into the e-CRF for both influenza positive and influenza negative cases on a weekly basis. Sites with sequencing capacity should upload data in GISAID on a weekly basis. Sites using the GIHSN sequencing platform should be able to have their samples shipped in regular batches at least 3 weeks before the WHO strain selection meeting.
- Geographical representativeness: sites in countries under-represented in GISAID will be given funding priority

Cost-effectiveness: the relevance of the cost in relation to expected sample size will be considered. The Foundation is providing catalytic funding and is not expected to fund the full cost of the clinical and sequencing data collection. In September, the Executive committee of the Foundation will select institutions and the amount of the grant provided during the season in order to support the implementation.

A formal letter from the Foundation describing grant modalities and payment milestones will be sent to the sites selected by mid October 2020.

² [GISAID - from Vision to Reality Eurosurveillance, 22\(13\) doi:10.2807/1560-7917.ES.2017.22.13.30494](https://doi.org/10.2807/1560-7917.ES.2017.22.13.30494) ;

HOW TO APPLY

The call has been posted on the www.gihsn.org website on June 8th, 2020.

All applications have to be submitted on-line on the GIHSN website **before July 17th, 2020** via the application template.

Requirements for applicants:

To be eligible, applicants should be not-for-profit public institutions.

The following documents should be provided along with the proposal to attest the above status:

- Last annual report
- Financial report (including earnings and balance sheet) from last year
- Bank account number (official bank document – with swift number)
- List of the members of the board of governors (i.e. group of people who jointly oversee the activities of the laboratory)
- Copy of the decree of creation (i.e. Statutory act returned by the president of the republic or the head of government)

The data sharing modality document (*See appendix 2*) will be requested to be signed by the selected sites at the start of the season.

Abbreviations

GIHSN Global Influenza Hospital Surveillance Network

GISAID Global Initiative on Sharing All Influenza Data

GISRS Global Influenza Surveillance and Response System

IFPMA International Federation of Pharmaceutical Manufacturers & Associations

WHO World Health Organisation

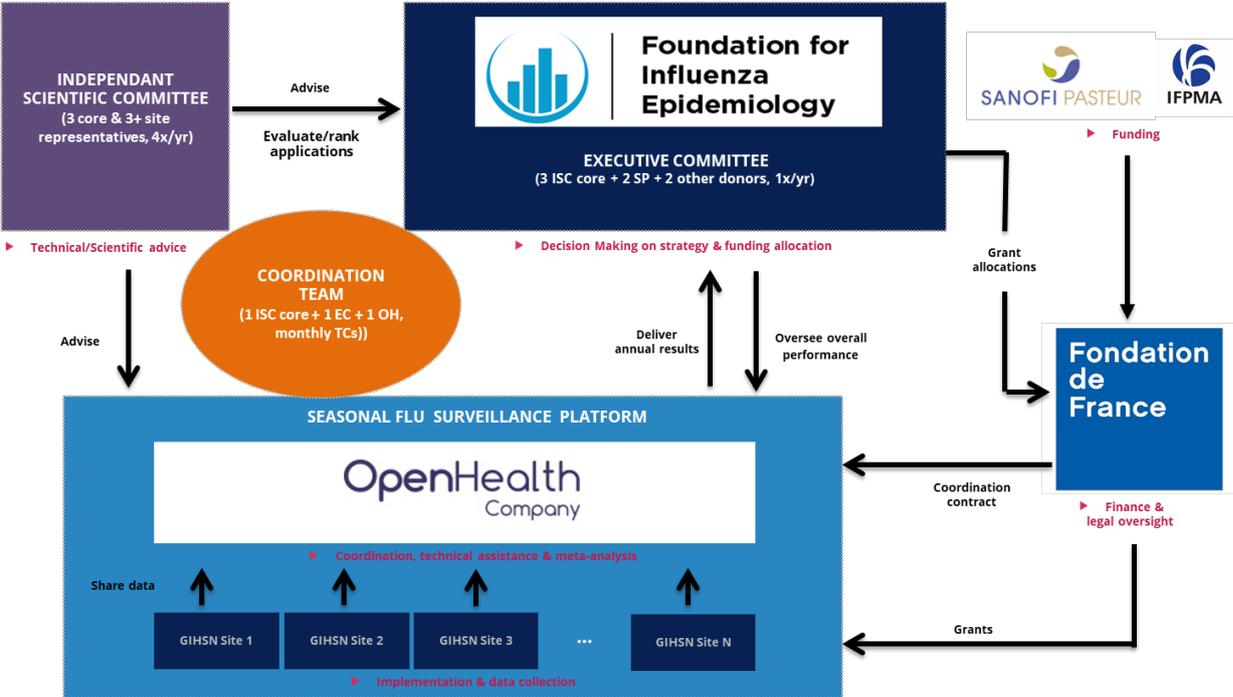
Appendix 1: Governance of the Foundation for Influenza Epidemiology

The governance of the Foundation for Influenza Epidemiology is ensured by an **Executive Committee (EC)**. The Executive Committee is the decision maker, in charge of the strategic directions related to the project. Based on pre-established criteria, the Executive Committee selects applicant sites for funding allocation each year. The Executive Committee is composed of two Sanofi Pasteur scientific specialists and three independent experts. Two seats are available for other potential donors.

An **Independent Scientific Committee** composed of 10 experts³ provide recommendations for technical, scientific and related ethical aspects to the Foundation. 3 of these experts are members of the Executive Committee.

OpenHealth is a subcontractor of the Foundation for Influenza Epidemiology and supports GIHSN operations.

More details on the Foundation are available on www.gihsn.org



³ Melissa Andrew (GIHSN Canada investigator), Elena Burtseva (GIHSN Moscow investigator), Allen Cheng (Monash Univ, Australia), Jill Ferdinand (CDC, USA), Bruno Lina (Univ of Lyon, France), Feng Luzhao (CDC, China), Marta Nunes (GIHSN South Africa investigator), Justin Ortiz (Univ of Maryland, USA), John Paget (NIVEL, Nederland) , Bobby Reiner (IHME, USA)
 Foundation for Influenza Epidemiology - GIHSN Call for tender 2020-2021

Appendix 2: Global Influenza Hospital Surveillance Network (GIHSN) data sharing agreement

Sites implementing the GIHSN protocol should be compliant with their ethical and national regulations for conducting the surveillance.

With respect to existing WHO surveillance capacities, I understand that all data collected through the GIHSN Study questionnaires will be shared with corresponding National Influenza Centers and/or with WHO Collaborating Centers for Reference and Research on Influenza. Influenza strain genetic sequencing data will be shared via [GISAID](#).

Open Health Company based in France, is responsible for the coordination of the GIHSN network on behalf of the Foundation for Influenza Epidemiology and is proposing an online data collection tool to ensure timely data display on the GIHSN website. Any obligation related to data protection and data transfer to the Open Health Company platform should be anticipated.

Data collected by sites receiving funding remains the proprietary of the site. There is no commercial use of the data. Sanofi Pasteur does not have access to the data. The data are transferred through a secured channel and the site has full access to the data through a secured platform managed by Open Health Company.

Open Health Company is given **access** to the GIHSN data for epidemiological research fulfilling the **three** following conditions:

- Analyses can only be performed for research purposes in line with the mandate of the Foundation (i.e. surveillance and monitoring of influenza viruses)
- Analyses are exclusively performed with strictly anonymous and aggregated data
- Any analyses plan will need to be approved **beforehand** by the Independent Scientific Committee of the Foundation

Analysis results will be submitted for publication. Scientific publications and communications will mention contributing sites with investigators names in the authorship in line with the ICMJE rules.

Sites will be informed upfront for any planned data analysis beyond the routine annual pooled analysis and **they have the possibility to opt-out**.

Considering these rules and in order to allow for continued analysis of both historical and current seasonal data, I hereby agree to share with Open Health Company the data collected at site level.

Main investigator First and Last Name	
Name and address of institution	
Country/region	

Date

Signature
